



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/641,931	08/18/2000	Christian Lanctot	2003390-0001	7406

7590 10/18/2002

Choate Hall & Stewart
Exchange Place
53 State Street
Boston, MA 02109-2891

EXAMINER

EPPERSON, JON D

ART UNIT

PAPER NUMBER

1639

DATE MAILED: 10/18/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary <i>F/c Copy</i>	Application No.	Applicant(s)	
	09/641,931	LANCOT ET AL.	
	Examiner	Art Unit	
	Jon D Epperson	1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on ____.

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) ____ is/are pending in the application,

4a) Of the above claim(s) ____ is/are withdrawn from consideration.

5) Claim(s) ____ is/are allowed.

6) Claim(s) ____ is/are rejected.

7) Claim(s) ____ is/are objected to.

8) Claim(s) 1-43 are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on ____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on ____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. ____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) <input type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____ .
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____ .	6) <input type="checkbox"/> Other: _____

DETAILED ACTION

Please Note: In an effort to enhance communication with our customers and reduce processing time, Group 1627 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your responses. The fax number is (703) 308-4315. A fax cover sheet is attached to this Office Action for your convenience. We encourage your participation in this Pilot program. If you have any questions or suggestions please contact Andrew Wang, Supervisory Patent Examiner, at (703) 306-3217. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.

Please note: The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to **Group Art Unit 1639**.

1. Please note also that in preparing this Restriction Requirement the Examiner noted a problem with claim 43. Claim 43 refers to the “N-terminal amino acid sequence” of claim 41; however, claim 41 does not refer to any “N-terminal amino acid sequence.” As a result, the Examiner has interpreted claim 43 to refer to the “N-terminal amino acid sequence” of claim 42 for the purposes of this Restriction Requirement. It would assist the further examination of this case on the merits if applicant could correct and/or address this problem in the Response to this action by changing claim 43 to read “The N-terminal amino acid sequence of claim 42 ...”

Election/Restriction

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-17, drawn to a method for “selecting a nucleic acid having a desired feature”, classified variously in class 435, subclass 69.1, 243, 320.1 and 325.

- II. Claims 18-19, drawn to a second method for “selecting a nucleic acid having a desired feature”, classified variously in class 435, subclass 69.1, 243, 320.1 and 325.
- III. Claims 20, drawn to a third method for “selecting a nucleic acid having a desired feature”, classified variously in class 435, subclass 69.1, 243, 320.1 and 325.
- IV. Claims 21-26, drawn to a method for “selecting a nucleic acid encoding a signal peptide or a protein having a signal peptide”, classified variously in class 435, subclass 69.1, 243, 320.1 and 325.
- V. Claims 27-32, drawn to a method for “selecting a nucleic acid encoding a protease, or encoding a protein or a peptide having a proteolytic activity”, classified variously in class 435, subclass 69.1, 243, 320.1 and 325.
- VI. Claims 33, drawn to a method for “selecting a nucleic acid encoding a drug-resistance protein or peptide”, classified variously in class 435, subclass 69.1, 243, 320.1 and 325.
- VII. Claim 34, drawn to a method for “for selecting a nucleic acid having a desired feature” using a virus, classified variously in class 435, subclass 69.1, 243, 320.1 and 325.
- VIII. Claims 35-40, drawn to a product described as “an isolated nucleic acid molecule encoding a dysfunctional viral genome”, classified in class 536, subclass 23.1, 23.2, 23.4.
- IX. Claims 41 and 43, drawn to a kit for “selecting a nucleic acid having a desired feature”, classified in class 435, subclass 975.

X. Claim 42, drawn to a product described as an “isolated N-terminal amino acid sequence encoding a dysfunctional signal peptide of a viral envelope protein”, classified in class 530, subclass 350.

3. The inventions are distinct, each from the other because of the following reasons:

4. Groups I-X represent separate and patentably distinct inventions. Groups VIII-X are drawn to different products and Groups I-VII are drawn to different methods (i.e., e.g., which are directed to different purposes, use different materials, recite different method or process steps for the preparation of different product(s), screening of different characteristics, such as different binding affinities, different biochemical reaction conditions, etc. or lead to different final results). Therefore, the groups that describe these products and methods have different issues regarding patentability and enablement, and represent patentably distinct subject matter, which merits separate and burdensome searches. Art anticipating or rendering obvious each of the above-identified groups respectively would not necessarily anticipate or render obvious another group, because they are drawn to different inventions that have different distinguishing features and/or characteristics. Each group will support separate patents.

5. For example, Groups I-VII represent separate and patentably distinct methods. The methods are distinct because they use different steps, require different reagents and/or will produce different results. In the instant case, Group VII requires “inserting an exogenous nucleic acid into a viral genome to provide a recombinant viral genome, and wherein said recombinant

Art Unit: 1639

viral genome is capable of producing a viral particle solely if said exogenous nucleic acid has the desired feature”, which is a step that is not required by the methods of Groups I-VI. Group VI requires method steps for “selecting a nucleic acid encoding a drug-resistance protein or peptide”, which are steps that are not required by the methods of Groups I-V and VII. Group V requires method steps for “selecting a nucleic acid encoding a protease, or encoding a protein or a peptide having a proteolytic activity”, which are steps that are not required by the methods of Groups I-IV and VI-VII. Group IV requires method steps for “selecting a nucleic acid encoding a signal peptide or a protein having a signal peptide”, which is a step that is not required by the methods of Groups I-III and V-VII. Group III requires method steps for “selecting a nucleic acid having a desired feature” using “a plasmid comprising a viral genome encoding a viral particle”, which are steps that are not required by the methods of Groups I-II and IV-VII. Group II requires “selecting a nucleic acid having a desired feature” using “suitable host” wherein “said exogenous nucleic acid, auto replicates and packages copies of itself into a plurality of recombinant viral particles”, which is a step that is not required by the methods of Groups I and III-VII. Therefore, Groups I-VII have different issues regarding patentability and enablement and represent patentably distinct subject matter.

6. Furthermore, Groups VIII-X represent patentably distinct products. Groups VIII-X represent separate and patentably distinct products because they differ in respect to their properties, their use and the synthetic methodology for making them. For example, Group X is drawn to an “isolate N-terminal amino acid sequence encoding a dysfunctional signal peptide of a viral envelop protein”, which requires different reagents and/or materials than Groups VIII and

Art Unit: 1639

IX. Likewise, Group IX is drawn to a “kit” for selecting a nucleic acid having a desired feature, which requires different reagents and/or materials than Groups VIII and X. Therefore, art anticipating or rendering obvious each of the above-identified groups respectively would not necessarily anticipate or render obvious another group, because they are drawn to different inventions that have different distinguishing features and/or characteristics. Consequently, Groups VIII-X have different issues regarding patentability and enablement and represent patentably distinct subject matter.

7. Finally, Groups I-X represent separate and distinct inventions because Group I-VII claims methods while Group VIII-X claims products. However, if applicant were to argue that any of the Groups were somehow related as product and process of use, the inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product(s) as claimed (i.e., Groups VIII-X) can be used in materially different process of using that product (MPEP § 806.05(h)), for example, the products (i.e., Groups VIII-X) could be used as nucleic acid probes.

8. These inventions have acquired a separate status in the art as shown by their different classification and/or divergent subject matter. The different methods and products would require completely different searches in both the patent and non-patent databases, and there is no

Art Unit: 1639

expectation that the searches would be coextensive. Therefore, this does create an undue search burden, and restriction for examination purposes as indicated is proper.

9. This application contains claims directed to patentably distinct species of the claimed invention for Groups I-X. Election is required as follows.

10. If applicant elects the invention of Group I, applicant is required to elect from the following patentably distinct species. Claim 1 is generic.

Subgroup 1: Species of viral genome (see claims 1,3,5,13,14,15)

Applicant must elect, for the purposes of search, a *single species* of viral genome. Furthermore, applicant must indicate which claims read on the elected species i.e., which claims read only on the elected species of subgroup 1.

Subgroup 2: Species of host (see claim 1)

Applicant must elect, for the purposes of search, a *single species* of host. Furthermore, applicant must indicate which claims read on the elected species i.e., which claims read only on the elected species of subgroup'2.

Subgroup 3: Species of exogenous nucleic acid (see claim 1,4,11)

Applicant must elect, for the purposes of search, a *single species* of exogenous nucleic acid. Furthermore, applicant must indicate which claims read on the elected species i.e., which claims read only on the elected species of subgroup 3.

Subgroup 4: Species of suppressive condition (see claims 1,2)

Applicant must elect, for the purposes of search, a *single species* of suppressive condition. Furthermore, applicant must indicate which claims read on the elected species i.e., which claims read only on the elected species of subgroup 4.

Subgroup 5: Species of desired feature (see claims 1,6)

Art Unit: 1639

Applicant must elect, for the purposes of search, a single species of desired feature. Furthermore, applicant must indicate which claims read on the elected species i.e., which claims read only on the elected species of subgroup 5.

Subgroup 6: Species of substance inhibiting viral packaging (see claims 2,6)

Applicant must elect, for the purposes of search, a single species of substance inhibiting viral packaging. Furthermore, applicant must indicate which claims read on the elected species i.e., which claims read only on the elected species of subgroup 6. **Please note:** Subgroup 6 does not have to be elected if the above election of a suppressive condition i.e., subgroup 4 does not apply.

Subgroup 7: Species of transfection (see claims 1,8,9)

Applicant must elect, for the purposes of search, a single species of transfection. Furthermore, applicant must indicate which claims read on the elected species i.e., which claims read only on the elected species of subgroup 7.

Subgroup 8: Species of nucleic acid origin (see claims 1,11,12)

Applicant must elect, for the purposes of search, a single species of nucleic acid origin. Furthermore, applicant must indicate which claims read on the elected species i.e., which claims read only on the elected species of subgroup 8.

11. If applicant elects the invention of Group II, applicant is required to elect from the following patentably distinct species. Claim 18 is generic.

Subgroup 1: Species of viral genome (see claim 18)

Applicant must elect, for the purposes of search, a single species of viral genome. Furthermore, applicant must indicate which claims read on the elected species i.e., which claims read only on the elected species of subgroup 1.

Subgroup 2: Species of host (see claim 18)

Applicant must elect, for the purposes of search, a single species of host. Furthermore, applicant must indicate which claims read on the elected species i.e., which claims read only on the elected species of subgroup 2.

Subgroup 3: Species of exogenous nucleic acid (see claim 18)

Art Unit: 1639

Applicant must elect, for the purposes of search, a single species of exogenous nucleic acid. Furthermore, applicant must indicate which claims read on the elected species i.e., which claims read only on the elected species of subgroup 3.

Subgroup 4: Species of suppressive condition (see claim 18, 19)

Applicant must elect, for the purposes of search, a single species of suppressive condition. Furthermore, applicant must indicate which claims read on the elected species i.e., which claims read only on the elected species of subgroup 4.

Subgroup 5: Species of desired feature (see claim 18)

Applicant must elect, for the purposes of search, a single species of desired feature. Furthermore, applicant must indicate which claims read on the elected species i.e., which claims read only on the elected species of subgroup 5.

Subgroup 6: Species of substance inhibiting viral packaging (see claim 18)

Applicant must elect, for the purposes of search, a single species of substance inhibiting viral packaging. Furthermore, applicant must indicate which claims read on the elected species i.e., which claims read only on the elected species of subgroup 6. **Please note:** Subgroup 6 does not have to be elected if the above election of a suppressive condition i.e., subgroup 4 does not apply.

Subgroup 7: Species of transfection (see claim 18)

Applicant must elect, for the purposes of search, a single species of transfection. Furthermore, applicant must indicate which claims read on the elected species i.e., which claims read only on the elected species of subgroup 7.

Subgroup 8: Species of nucleic acid origin (see claim 18)

Applicant must elect, for the purposes of search, a single species of nucleic acid origin. Furthermore, applicant must indicate which claims read on the elected species i.e., which claims read only on the elected species of subgroup 8.

12. If applicant elects the invention of Group III, applicant is required to elect from the following patentably distinct species. Claim 20 is generic.

Subgroup 1: Species of viral genome (see claim 20)

Applicant must elect, for the purposes of search, a single species of viral genome. Furthermore, applicant must indicate which claims read on the elected species i.e., which claims read only on the elected species of subgroup 1.

Subgroup 2: Species of plasmid (see claim 20)

Applicant must elect, for the purposes of search, a single species of plasmid. Furthermore, applicant must indicate which claims read on the elected species i.e., which claims read only on the elected species of subgroup 2.

Subgroup 3: Species of exogenous nucleic acid (see claim 20)

Applicant must elect, for the purposes of search, a single species of exogenous nucleic acid. Furthermore, applicant must indicate which claims read on the elected species i.e., which claims read only on the elected species of subgroup 3.

Subgroup 4: Species of inactivating the packaging ability of viral genome (see claim 20)

Applicant must elect, for the purposes of search, a single species of inactivating the packaging ability of viral genome. Furthermore, applicant must indicate which claims read on the elected species i.e., which claims read only on the elected species of subgroup 4.

Subgroup 5: Species of desired feature (see claim 20)

Applicant must elect, for the purposes of search, a single species of desired feature. Furthermore, applicant must indicate which claims read on the elected species i.e., which claims read only on the elected species of subgroup 5.

Subgroup 6: Species of suitable host (see claim 20)

Applicant must elect, for the purposes of search, a single species of suitable host. Furthermore, applicant must indicate which claims read on the elected species i.e., which claims read only on the elected species of subgroup 6.

Subgroup 7: Species of transfection (see claim 20)

Applicant must elect, for the purposes of search, a single species of transfection. Furthermore, applicant must indicate which claims read on the elected species i.e., which claims read only on the elected species of subgroup 7.

Subgroup 8: Species of nucleic acid origin (see claim 20)

Art Unit: 1639

Applicant must elect, for the purposes of search, a single species of nucleic acid origin. Furthermore, applicant must indicate which claims read on the elected species i.e., which claims read only on the elected species of subgroup 8.

13. If applicant elects the invention of Group IV, applicant is required to elect from the following patentably distinct species. Claim 21 is generic.

Subgroup 1: Species of viral genome (see claims 21,22,26)

Applicant must elect, for the purposes of search, a single species of viral genome. Furthermore, applicant must indicate which claims read on the elected species i.e., which claims read only on the elected species of subgroup 1.

Subgroup 2: Species of host (see claim 21)

Applicant must elect, for the purposes of search, a single species of host. Furthermore, applicant must indicate which claims read on the elected species i.e., which claims read only on the elected species of subgroup 2.

Subgroup 3: Species of exogenous nucleic acid (see claim 21)

Applicant must elect, for the purposes of search, a single species of exogenous nucleic acid. Furthermore, applicant must indicate which claims read on the elected species i.e., which claims read only on the elected species of subgroup 3.

Subgroup 4: Species of inactivating the packaging ability of viral genome (see claim 21)

Applicant must elect, for the purposes of search, a single species of inactivating the packaging ability of viral genome. Furthermore, applicant must indicate which claims read on the elected species i.e., which claims read only on the elected species of subgroup 4.

Subgroup 5: Species of signal peptide (see claims 21,24)

- A. SAAPLVTAMCRSGNVS
- B. SAAPLVTAMCGSGNVS

Applicant must elect, for the purposes of search, a single species of signal peptide from the list above. Furthermore, applicant must indicate which claims read on the elected species i.e., which claims read only on the elected species of subgroup 5.

Subgroup 6: Species of transfection (see claims 21,25)

Applicant must elect, for the purposes of search, a *single species* of transfection. Furthermore, applicant **must** indicate which claims read on the elected species i.e., which claims read **only** on the elected species of subgroup 6.

Subgroup 7: Species of signal peptide dysfunction (see claim 23)

Applicant must elect, for the purposes of search, a *single species* of signal peptide dysfunction. Furthermore, applicant **must** indicate which claims read on the elected species i.e., which claims read **only** on the elected species of subgroup 7.

14. If applicant elects the invention of Group V, applicant is required to elect from the following patentably distinct species. Claim 27 is generic.

Subgroup 1: Species of viral genome (see claims 27,31)

Applicant must elect, for the purposes of search, a *single species* of viral genome. Furthermore, applicant **must** indicate which claims read on the elected species i.e., which claims read **only** on the elected species of subgroup 1.

Subgroup 2: Species of host (see claim 27)

Applicant must elect, for the purposes of search, a *single species* of host. Furthermore, applicant **must** indicate which claims read on the elected species i.e., which claims read **only** on the elected species of subgroup 2.

Subgroup 3: Species of exogenous nucleic acid (see claim 27)

Applicant must elect, for the purposes of search, a *single species* of exogenous nucleic acid. Furthermore, applicant **must** indicate which claims read on the elected species i.e., which claims read **only** on the elected species of subgroup 3.

Subgroup 4: Species of fetter protein (see claim 27)

Applicant must elect, for the purposes of search, a *single species* of fetter protein. Furthermore, applicant **must** indicate which claims read on the elected species i.e., which claims read **only** on the elected species of subgroup 4.

Subgroup 5: Species of structural protein (see claims 27,32)

Applicant must elect, for the purposes of search, a single species of structural protein. Furthermore, applicant must indicate which claims read on the elected species i.e., which claims read only on the elected species of subgroup 5.

Subgroup 6: Species of transfection (see claim 27)

Applicant must elect, for the purposes of search, a single species of transfection. Furthermore, applicant must indicate which claims read on the elected species i.e., which claims read only on the elected species of subgroup 6.

Subgroup 7: Species of protease (see claim 27)

Applicant must elect, for the purposes of search, a single species of protease. Furthermore, applicant must indicate which claims read on the elected species i.e., which claims read only on the elected species of subgroup 7.

Subgroup 8: Species of protease cleavage site (see claim 29)

Applicant must elect, for the purposes of search, a single species of protease cleavage site. Furthermore, applicant must indicate which claims read on the elected species i.e., which claims read only on the elected species of subgroup 8.

15. If applicant elects the invention of Group VI, applicant is required to elect from the following patentably distinct species. Claim 33 is generic.

Subgroup 1: Species of viral genome (see claim 33)

Applicant must elect, for the purposes of search, a single species of viral genome. Furthermore, applicant must indicate which claims read on the elected species i.e., which claims read only on the elected species of subgroup 1.

Subgroup 2: Species of host (see claim 33)

Applicant must elect, for the purposes of search, a single species of host. Furthermore, applicant must indicate which claims read on the elected species i.e., which claims read only on the elected species of subgroup 2.

Subgroup 3: Species of exogenous nucleic acid (see claim 33)

Applicant must elect, for the purposes of search, a single species of exogenous nucleic acid. Furthermore, applicant must indicate which claims read on the elected species i.e., which claims read only on the elected species of subgroup 3.

Subgroup 4: Species of drug-resistant protein or peptide (see claim 33)

Applicant must elect, for the purposes of search, a single species of drug-resistant protein or peptide. Furthermore, applicant must indicate which claims read on the elected species i.e., which claims read only on the elected species of subgroup 4.

Subgroup 5: Species of substance inhibiting viral packaging functions (see claims 33)

Applicant must elect, for the purposes of search, a single species of substance inhibiting viral packaging functions. Furthermore, applicant must indicate which claims read on the elected species i.e., which claims read only on the elected species of subgroup 5.

Subgroup 6: Species of transfection (see claim 33)

Applicant must elect, for the purposes of search, a single species of transfection. Furthermore, applicant must indicate which claims read on the elected species i.e., which claims read only on the elected species of subgroup 6.

16. If applicant elects the invention of Group VII, applicant is required to elect from the following patentably distinct species. Claim 34 is generic.

Subgroup 1: Species of viral genome (see claim 34)

Applicant must elect, for the purposes of search, a single species of viral genome. Furthermore, applicant must indicate which claims read on the elected species i.e., which claims read only on the elected species of subgroup 1.

Subgroup 2: Species of desired feature (see claim 34)

Applicant must elect, for the purposes of search, a single species of desired feature. Furthermore, applicant must indicate which claims read on the elected species i.e., which claims read only on the elected species of subgroup 2.

Subgroup 3: Species of exogenous nucleic acid (see claim 34)

Art Unit: 1639

Applicant must elect, for the purposes of search, a single species of exogenous nucleic acid. Furthermore, applicant must indicate which claims read on the elected species i.e., which claims read only on the elected species of subgroup 3.

17. If applicant elects the invention of Group VIII, applicant is required to elect from the following patentably distinct species. Claim 35 is generic.

Subgroup 1: Species of nucleic acid (see claims 35, 37-40)

Applicant must elect, for the purposes of search, a single species of isolated nucleic acid encoding dysfunctional viral genome. Applicant must also provide a SEQ ID No. for the single elected species. Furthermore, applicant must indicate which claims read on the elected species i.e., which claims read only on the elected species of subgroup 1.

Subgroup 2: Species of desired feature (see claim 35)

Applicant must elect, for the purposes of search, a single species of desired feature. Furthermore, applicant must indicate which claims read on the elected species i.e., which claims read only on the elected species of subgroup 2.

Subgroup 3: Species of exogenous nucleic acid (see claim 35)

Applicant must elect, for the purposes of search, a single species of exogenous nucleic acid. Applicant must also provide a SEQ ID No. for the single elected species. Furthermore, applicant must indicate which claims read on the elected species i.e., which claims read only on the elected species of subgroup 3.

Subgroup 4: Species of suitable host (see claim 35)

Applicant must elect, for the purposes of search, a single species of suitable host. Furthermore, applicant must indicate which claims read on the elected species i.e., which claims read only on the elected species of subgroup 4.

Subgroup 5: Species of nucleic acid (see claim 36)

- A. Nucleic acid encoding a signal peptide
- B. Nucleic acid encoding at least partially for a protein having a signal peptide
- C. Nucleic acid encoding proteases
- D. Nucleic acid encoding proteins or peptides having a proteolytic activity

Art Unit: 1639

E. Nucleic acid encoding drug-resistance proteins or peptides

Applicant must elect, for the purposes of search, a *single species* of nucleic acid from the list above i.e., Subgroup 5. Furthermore, applicant *must* indicate which claims read on the elected species i.e., which claims read *only* on the elected species of subgroup 5.

18. If applicant elects the invention of Group IX, applicant is required to elect from the following patentably distinct species. Claim 41 is generic.

Subgroup 1: Species of isolated nucleic acid (see claims 41)

Applicant must elect, for the purposes of search, a *single species* of isolated nucleic acid encoding dysfunctional viral genome. Applicant *must* also provide a *SEQ ID No.* for the single elected species. Furthermore, applicant *must* indicate which claims read on the elected species i.e., which claims read *only* on the elected species of subgroup 1.

Subgroup 2: Species of desired feature (see claim 41)

Applicant must elect, for the purposes of search, a *single species* of desired feature. Furthermore, applicant *must* indicate which claims read on the elected species i.e., which claims read *only* on the elected species of subgroup 2.

Subgroup 3: Species of exogenous nucleic acid (see claim 41)

Applicant must elect, for the purposes of search, a *single species* of exogenous nucleic acid. Applicant *must* also provide a *SEQ ID No.* for the single elected species. Furthermore, applicant *must* indicate which claims read on the elected species i.e., which claims read *only* on the elected species of subgroup 3.

Subgroup 4: Species of enzyme (see claim 41)

Applicant must elect, for the purposes of search, a *single species* of suitable host. Furthermore, applicant *must* indicate which claims read on the elected species i.e., which claims read *only* on the elected species of subgroup 4.

Subgroup 5: Species of probe (see claim 41)

Applicant must elect, for the purposes of search, a *single species* of suitable host. Furthermore, applicant *must* indicate which claims read on the elected species i.e., which claims read *only* on the elected species of subgroup 5.

Art Unit: 1639

Subgroup 6: Species of probe (see claim 41)

Applicant must elect, for the purposes of search, a single species of suitable host. Furthermore, applicant must indicate which claims read on the elected species i.e., which claims read only on the elected species of subgroup 6.

19. If applicant elects the invention of Group X, applicant is required to elect from the following patentably distinct species. Claim 42 is generic.

Subgroup 1: Species of isolated N-terminal amino acid sequence (see claims 42, 43)

Applicant must elect, for the purposes of search, a single species of isolated N-terminal amino acid sequence. Applicant must also provide a SEQ ID No. for the single elected species. Furthermore, applicant must indicate which claims read on the elected species i.e., which claims read only on the elected species of subgroup 1.

20. The species are distinct, each from the other, because their structures and modes of action are different. They would also differ in their reactivity and the starting materials from which they are made. For different species of method, the method steps for each species would differ. Moreover, the above species can be separately classified. Consequently, the species have different issues regarding patentability and represent patentably distinct subject matter. Therefore, this does create an undue search burden, and election for examination purposes as indicated is proper.

21. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

22. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

23. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

24. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

25. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the

Art Unit: 1639

examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

26. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.43). Because the above restriction/election requirement is complex, a telephone call to applicants to request an oral election was not made. See MPEP § 812.01.

27. Applicant is reminded that upon cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

28. Applicant is also reminded that a 1 – month (not less than 30 days) shortened statutory period will be set for response when a written requirement is made without an action on the merits. This period may be extended under the provisions of 37 CFR 1.136(a). Such action will not be an “action on the merits” for purposes of the second action final program, see MPEP 809.02(a).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jon D Epperson whose telephone number is (703) 308-2423. The examiner can normally be reached Monday through Friday from 8:30 a.m. to 4:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang, can be reached on (703) 306-3217. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-2439.

Jon D. Epperson, Ph.D.
October 16, 2002

BENNETT CELSA
PRIMARY EXAMINER

